#### REMARKS

### I. <u>INTRODUCTION</u>

Applicants thank the Examiner for the indication that claims 26, 70, 71, 82 and 83 are allowed, and that claims 4, 21-25, 41-43, 62-69, 73-82, 84 and 85 would be allowed if rewritten in independent form. Claim 82 has been amended above to remove minor informalities therefrom, and not for any reason relating to patentability thereof. Claims 1-4, 7-10, 12-27, 39-43, 62-69 and 72-85 are under consideration in the above-referenced application. Provided above, please find a claim listing indicating the current amendment to the previously-pending claim 82 on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

## II. OBJECTION TO CLAIM 82 SHOULD BE WITHDRAWN

Claim 82 stands objected to as excluding the recitation of "method" therein. As the Examiner shall ascertain, claim 82 has been amended above to include such recitation. Accordingly, the objection to claim 82 is now moot, and should therefore be withdrawn.

## III. REJECTIONS UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN

Claims 1-3, 7-10, 12-20, 27, 39, 40 and 72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zimnyakov et al., "Spatial speckle correlometry in applications to issue structure monitoring," Applied Optics, Col. 36, No. 22, August 1, 1997, pp. 5594-5607 (the "Zimnyakov publication"), in view of U.S. Patent No. 6,324,419 issued to Guzelsu et al. (the "Guzelsu Patent") and U.S. Patent No. 5,735,276 issued to Lemelson (the "Lemelson Patent").

In order for a claim to be rejected for obviousness under 35 U.S.C. § 103, not only must the prior art teach or suggest each element of the claim, the prior art must also suggest combining the elements in the manner contemplated by the claim. See Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934 (Fed. Cir.), cert. denied 111 S.Ct. 296 (1990); see In re Bond, 910 F.2d 831, 834 (Fed. Cir. 1990). "It is improper to use the inventor's disclosure as a road map for selecting and combining prior art disclosures." See Grain Processing Corp. v. American Maize-Products Corp., 840 F.2d 902, 907 (Fed. Cir. 1988). "[T]he reference must be viewed without the benefit of hindsight afforded to the disclosure." In re Paulsen, 30 F.3d 1475, 1482 (Fed.Cir. 1994). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. See In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991).

Applicants' invention, as recited in independent claim 1, relates to a method of analyzing tissue, which comprises the steps of, *inter alia*:

illuminating a tissue with coherent or partially coherent light;

receiving light reflected from the tissue at a detector and forming series of speckle patterns; and

analyzing changes in the speckle patterns at time intervals sufficient to measure changes caused by microscopic motion of objects within the tissue, wherein the tissue is at least one of in vivo or an internal tissue.

Applicants' invention, as recited in independent claim 39, relates to a method of analyzing a tissue structure, which comprises the steps of, *inter alia*:

illuminating the tissue structure with coherent or partially coherent light;

receiving light reflected from the tissue structure at a detector and forming a series of speckle patterns;

gathering speckle pattern data at time intervals sufficient to measure microscopic motion within the tissue structure or adjacent tissue; and

assessing the tissue structure by analyzing spatial characteristics of the speckle pattern data to deduce structural or biomechanical characteristics of the tissue structure, wherein the tissue structure is at least one of in vivo or an internal tissue structure.

In the Office Action dated January 6, 2006, the Examiner states that the Zimnyakov publication only disclosed that the techniques described therein "was carried out in vitro." (See Office Action dated January 6, 2006, p. 2, ln. 26). Thus, the Examiner effectively admitted that the Zimnyakov publication fails to teach, suggest or disclose analyzing changes in the speckle patterns at time intervals sufficient to measure changes caused by microscopic motion of objects within the tissue (which is in vivo and/or an internal tissue), as recited in independent claim 1, or assessing the tissue structure by analyzing spatial characteristics of the speckle pattern data to deduce structural or biomechanical characteristics of the tissue structure (which is in vivo and/or an internal tissue), as recited in independent claim 39.

However, the Examiner contends that the Guzelsu Patent performs an analysis invivo, and that the Lemelson Patent describes the testing of skin and internal tissues. (See *id.*, p. 2, ln. 26 to p. 3, ln. 1). Then, the Examiner stated that "[i]t would have been obvious to one skilled in the art to have carried out the method of Zimnyakov et al in-vivo as is a well known expedient in the art of optical tissue diagnosis and to either monitor the skin or internal tissue as taught by Lemelson." *Id.*, p. 3, lns. 1-4. Again, Applicants respectfully disagree.

As previously argued, it is respectfully asserted that there is no teach, suggestion, motivation or incentive to combine the Zimnyakov publication with the Guzelsu and Lemelson Patents in a manner contemplated by the Examiner. The Examiner is respectfully reminded that "[m]ultiple cited prior art references must suggest the desirability of being combined and the reference must be viewed without the benefit of hindsight afforded to the disclosure." (emphasis

added) In re Paulsen, 30 F.3d 1475, 1482 (Fed. Cir. 1994), emphasis added. "The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine the references in order to solve the problem. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 679 (Fed. Cir. 1998). Applicants respectfully submit that there is no motivation or incentive to make the combination of the references as indicated by the Examiner to allegedly teach or suggest Applicants' invention as recited in independent claims 1 and 39.

In particular, one of the objects of the present invention is "to characterize tissue by analyzing speckle patterns formed by light reflected from tissue." (Applicants' Specification, e.g., p. 1, lns.6-7). However, one of the objects of the Guzelsu Patent is "to provide an apparatus which produces a very small gage length or spot size of the light beam to enable measurement of soft tissue deformations in-vivo." (Guzelsu Patent, col. 4, lns. 7-10). Certain objects of the Lemelson Patent are "to provide a new and improved system and method for scanning and detecting or identifying select matter of a portion of matter containing such select matter and other matter, in mixture, as cellular tissue or otherwise combined ... [,] and detecting and indicating the presence of a select chemical and/or biological material, in a sample of matter or in tissue or body fluid of a living being." (Lemelson Patent, col. 4, lns. 25-34). Thus, the problem confronted by the inventor for the above-identified application is completely different than the problem confronted by the inventors in the Guzelsu and Lemelson Patents. Indeed, the Lemelson Patent has absolutely no mention of the use of speckle patterns associated with tissue structures.

In addition, neither the Guzelsu Patent nor the Lemelson Patent even remotely mention any reason or benefit to <u>analyze changes in the speckle patterns at time intervals sufficient</u> to measure changes caused by microscopic motion of objects within the internal or in-vivo tissue.

as recited in independent claim 1, or assess the tissue structure by analyzing spatial characteristics of the speckle pattern data to deduce structural or biomechanical characteristics of the internal or in-vivo tissue structure, as recited in independent claim 39. Merely because the Guzelsu Patent refers to the in-vivo analysis, and the Lemelson Patent mentions the selection and identification of matter in internal tissues, such indications do not provide any motivation or incentive to combine these references to the Zimnyakov publication to teach or suggest Applicants' invention as recited in independent claims 1 and 39. In the Final Office Action, the Examiner does not provide any such teach, suggestion, motivation or incentive to make the combination suggested therein. In addition, because the Examiner does not disagree with the detailed arguments provided herein above, it is assumed that the Examiner acknowledges that the problem confronted by Applicants is different from the problem confronted by the inventors in the Guzelsu and Lemelson Patents. Thus, it appears that the Examiner does not argue the impropriety of the combination of the Zimnyakov publication with the Guzelsu and Lemelson Patents.

Applicants further submit that "[i]t is improper to use the inventor's disclosure as a road map for selecting and combining prior art disclosures." See Grain Processing Corp. v. American Maize-Products Corp., 840 F.2d 902, 907 (Fed. Cir. 1988). "[T]he reference must be viewed without the benefit of hindsight afforded to the disclosure." In re Paulsen, supra. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not be based on Applicants' disclosure. See In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). Applicants respectfully submit that the Examiner is relying on an improper hindsight reconstruction, which cannot be used for rejecting the claims of the above-identified application. As indicated above, the Examiner does not even respond to this significant point.

Applicants are left to assume that the Examiner should agree with the point made by Applicants in the previous response.

In the Final Office Action, the Examiner further contends that "it is well known in the art to first perform a method in-vitro in an experimental set-up prior to in-vivo testing and the use of optical diagnostic methods in-vivo are old and well known results of first performing the test in-vitro." (Final Office Action, p. 3, Ins. 18-21). While it may be true that at times, tests may be performed first in-vitro, and then in-vivo. However, in the present case, there is absolutely no teaching or suggestion in the references relied on by the Examiner or known to those having ordinary skill in the art to use the conventional diagnostic methods in-vivo to perform the procedure described in the Zimnyakov publication (which only describes the in-vitro application).

Indeed, it is believed that the conventional diagnostic methods referenced by the Examiner in the Final Office Action could not contemplate performing an analysis of changes in the speckle patterns at time intervals sufficient to measure changes caused by microscopic motion of objects within the internal or in-vivo tissue, as recited in independent claim 1, or an assessment of the tissue structure by analyzing spatial characteristics of the speckle pattern data to deduce structural or biomechanical characteristics of the internal or in-vivo tissue structure, as recited in independent claim 39. Clearly, the Zimnyakov publication did not even indicate the possibility of using the procedure described therein for in-vivo applications. In fact, the application of such procedure of the Zimnyakov publication in-vivo could not be accomplished without undue experimentation by those having ordinary skill in the art at the time the present claimed invention was made. The Examiner's reasoning regarding the possibility of using the conventional diagnostic methods in-vivo for the procedure described in the Zimnyakov publication is faulty. In particular, in

certain cases, it is possible to first experiment on samples in-vitro and them move on to the application for the samples in-vivo. However, such cases do not extend to numerous applications which would require undue experimentation to utilize the procedure in-vivo, which is the case for the present invention as recited in independent claims 1 and 39.

Therefore, Applicants again respectfully asserts that there is no teaching, suggestion, motivation or incentive to combine the Zimnyakov publication with the Guzelsu Patent or the Lemelson Patent in a manner contemplated by the Examiner to teach or suggest the subject matter recited in independent claims 1 and 39. Further, it appears that the Examiner is employing an *improper hindsight* reconstruction for combining the Zimnyakov publication with the Guzelsu Patent or the Lemelson Patent to teach Applicants' invention as recited in these independent claims, which is inappropriate under the case law of the United States. Thus, the final §103(a) rejection of these claims and the claims which depend there from should be withdrawn.

Regarding certain other claims pending in the present application, it is respectfully asserted that various claims which depend from amended independent claims 1 and 39 are also allowable for at least the same reasons, as well as containing separately patentable subject matter. Indeed, the Examiner did not even mention the arguments provided in Applicants' previous response regarding claims 12, 14 and 18, and thus the same argument is submitted herein for affirmative review and consideration by the Examiner.

For example, claims 12 recites that a detector is located farther than one wavelength of light from the tissue and detects far field speckle, and claim 13 recites that the detector is located within one wavelength of light from the tissue and detects near field speckle.

None of the Zimnyakov publication, the Guzelsu Patent or the Lemelson Patent teaches or suggests

any such recited subject matter. In the Office Action of January 6, 2006, with respect to claim 13, the Examiner contends that the specific placement of the detector with respect to the tissue is merely a design choice. Applicants respectfully disagree, and point the Examiner to the recitations of these claims which specifically state that this placement of the detector allows the detector to detect far field speckle (claim 12) or near field speckle (claim 13), and the placement thereof is important for such detection, i.e., not merely a design choice. Accordingly, the subject matter recited in these claims is patentable over the references relied on by the Examiner for rejecting such claims.

With respect to claim 14, this claim recites an implementation of an analyzing step which comprises comparing each of the series of speckle patterns to a series of reference speckle patterns, and quantifying the temporal correlation differences between the speckle patterns and the reference patterns. Indeed, the Examiner is not pointing to any of the references relied thereby to reject these claims as including such subject matter. Accordingly, it is submitted that this subject matter is not contained in such references. Claims 15-17 which depend from claim 14 also include additional subject matter which is not taught or suggested by the references relied on by the Examiner, nor does the Examiner contends that they do.

Further, with respect to claim 18, this claim recites that the analyzing step further comprises analyzing spatial characteristics of the speckle pattern to deduce structural characteristics of the tissue. Again, the Examiner is not pointing to any of the references relied thereby to reject these claims as including such subject matter. Accordingly, it is submitted that this subject matter is not contained in such references.

# IV. <u>CONCLUSION</u>

In light of the foregoing, Applicants respectfully submit that all pending claims 1-4, 7-10, 12-27, 39-43, 62-69 and 72-85 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

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